

CONFIRMATION COPY  
VIA FACSIMILE

AOYAMA & PARTNERS

REGISTERED PATENT ATTORNEYS

O. Kawamiya  
Y. Tamura  
M. Tanaka  
H. Yamazaki  
Y. Shibata  
.....  
T. Aoyama  
Y. Furukawa  
.....  
M. Iwasaki, Ph.D.

Ms. Lisa M. Griffith  
THE GRIFFITH LAW FIRM, A P.C.  
13873 Carriage Road  
Poway, CA 92064  
U.S.A.

Office: IMP Building, 1-3-7, Shiomi, Chuo-ku  
Osaka, 540-0001 JAPAN  
Mail : Osaka Central P.O. Box 16, 530-8691 JAPAN  
Phone: (81)6-6949-1261  
E-Mail: info@aoyamapat.gr.jp  
Fax : (81)6-6949-0361(G3)/(81)6-6949-0362(G4)

September 15, 2004

VIA FACSIMILE

Your Ref: Sensory 0011.JP  
Our Ref: 156783  
Japanese Patent Application No. 520046/1996  
Applicant: Sensory Systems d/b/a Cosmederm Technologies

Dear Ms. Griffith:

With respect to the above-identified case, this is to advise you that an office action was issued on August 31, 2004.

In the office action, the following references were cited:

References which constitute the basis of the present office action:

- 1: JP-A-03/007215 (corresponding to EP 0 390 456 A2)
- 2: JP-B-46/035760 (no patent family; an English abstract attached)
- 3: US Patent No. 4,477,439
- 4: JP-A-02/022216 (corresponding to EP 0 346 957 A1)
- 5: WO 94/06440 (JP-A-08/501553)
- 6: JP-A-62/255406 (no patent family; an English abstract attached)

Copies of the office action, References 1-6 and their English counterpart(s) or abstract(s) will follow with the confirmatory copy of this letter.

Other references which do not constitute the basis of the present office action but indicate background prior art:

- A: JP-A-11/502504
- B: US Patent No. 4,943,432
- C: JP-A-07/267869
- D: JP-A-07/267870

[If you need copies of these references and their English counterpart(s) or abstract(s), please write to us so.]

Anticipating that you are handling the corresponding U.S. application(s) and in view of the Patent Term Guarantee Act of 1999 and the associated rules, i.e., 37 CFR 1.701-1.705, enacted in the United States, we hasten to inform you of the above references.

Briefly, the Examiner raised "novelty" and "obviousness" rejections on the basis of the above References 1-6. In addition, the Examiner raised a few objections to the description in the specification and claims.

BEST AVAILABLE COPY

T. Higuchi  
A. Itoh  
H. Ishii  
A. Yamamoto  
M. Wada  
M. Sumejima  
M. Ishino  
A. Maeda  
T. Yamada  
M. Yano  
Y. Kitahara  
T. Nakajima  
H. Takayama  
.....  
T. Abe  
(Lawyer)  
.....  
T. Omori  
S. Nakajima  
K. Kojima  
Y. Tsuboi  
T. Ueda, Ph.D.  
H. Seki, Ph.D.  
K. Tashiro  
M. Takeuchi  
T. Motoyama, Ph.D.  
M. Saito  
M. Ohsumi  
H. Kano  
M. Matsutani  
S. Genba  
Y. Maehori  
K. Morizumi  
C. Saito  
H. Nakano  
K. Inaba  
M. Nakatsuka  
Y. Ohata  
H. Tamura  
Y. Nakamura  
S. Nishishita  
K. Tomita, Ph.D.  
K. Takahashi  
S. Takayama  
H. Okazaki  
J. Kawabata  
H. Shinagawa, Ph.D.  
H. Goto  
M. Shinoda  
.....  
S. Amai  
E. Kaizaki

Office Action

issued on August 31, 2004

I. The application is to be rejected under Article 29, Paragraph 1 of the Patent Law (novelty) because the inventions of the following claims are disclosed in the following references.

Claims 1-6, 11-14 and 16-26/References 1 and 2

Example 2 of Reference 1 discloses a composition comprising a strontium salt and ethanol (organic alcohol), and Example 2 of Reference 2 discloses a composition comprising a strontium salt and sodium benzoate (carboxylic acid). The compositions of the above claims can not be distinguished from those of References 1 and 2, merely by the existence of the wordings "for topical application to a subject" and "for inhibiting skin irritation in a subject" in claims 1 and 2.

II. The application is to be rejected under Article 29, Paragraph 2 of the Patent Law (obviousness) because the inventions of the following claims would be obvious to those skilled in the art from the following references.

Claims 1-26/References 1-6

It would be obvious to those skilled in the art to add conventional additives to the compositions of References 1 and 2.

Reference 3 discloses the use of a strontium salt for treatment of soreness in the skin (Claims), and Reference 4 discloses the use of a water-soluble strontium compound as a tooth desensitizing agent (page 2, lines 27-41 in EP 0 346 957 A1). On the other hand, Reference 5 describes a salicylic acid derivative as an irritant ingredient in a cosmetic composition (page 2, second full paragraph and pages 9-12), and Reference 6 describes capsaicin as such an irritant ingredient (page 1, right lower column). Accordingly, it would be obvious to those skilled in the art to use a strontium salt for inhibition of skin irritation caused by the above irritant ingredients and to confirm the effects of the strontium salt experimentally.

III. The application is to be rejected under Article 36 of the Patent Law (insufficient disclosure) because of the following reasons.

- (a) The irritant ingredients which are specifically described in the present specification and of which the effects are confirmed are limited to  $\alpha$ -hydroxy acids such as lactic acid and glycolic acid,  $\beta$ -hydroxy acids such as capryloyl salicylic acid, capsaicin, peroxides such as benzoyl peroxide, and ocean water. On the other hand, the applicant describes in the specification (page 15, lines 18-22 in the English text) that "Agents which are effective to combat one source of sensory stimulus are ineffective against other sensory stimuli caused by an applied skin care product". If the applicant's recognition is a technically common knowledge on the priority date of the present application, it can not be said that a strontium salt is effective

BEST AVAILABLE COPY

against any other irritant ingredients than those listed above (claim 1) or against ordinary skin irritation (claim 2).

Consequently, the specification fails to describe the inventions of claims 1-26 so that those skilled in the art can carry out the inventions.

- (b) The term "irritant ingredient" in the claims is unclear because the range of ingredients encompassed by the term is vague under the circumstances in which a method of objectively evaluating the skin irritation is unclear.
- (c) The term "topical" in the claims is unclear because the range of application regions encompassed by the term is vague.
- (d) The term "about" used in claims 3 and 12 makes the scope of the invention defined in each claim unclear.

References cited

- 1: JP-A-03/007215 (corresponding to EP 0 390 456 A2)
  - 2: JP-B-46/035760 (no patent family; an English abstract attached)
  - 3: US Patent No. 4,477,439
  - 4: JP-A-02/022216 (corresponding to EP 0 346 957 A1)
  - 5: WO 94/06440 (JP-A-08/501553)
  - 6: JP-A-62/255406 (no patent family; an English abstract attached)
- [Copies of these references and their English counterpart(s) or abstract(s) were attached to our letter of September 15, 2004.]